

FORM 39A [(SEE RULE 150 E (f) UNDER THE DRUGS & COSMETICS ACT 1940 & RULES THEREUNDER)

Generic Name : Gentamicin Injection IP

Sample Name : Gentamicin Injection IP 10mg/ml

Submitted By : M/s Meghalayan Medical Drugs and Services Limited
(MMDSL)
New Colony Shillong, DHS Laitumkhrah, Office of the
Managing Director, MMDSL East Khasi Hills District
Meghalaya Shillong (Assam) 793003 District Meghalaya
Shillong (Assam) 793003

Format No : ██████████
Mfg. Lic.No. : ██████████

Report No. : ██████████
Date of Receipt : 18/04/2024
Report Date : 02/05/2024
Period of Analysis : 18/04/2024-02/05/2024
Stability Condition :

Mfd. By : NS
Supplied By : NS
Ref.No. : NS

Batch No.	Mfg. Date	Exp. Date	Batch Size	Sample Qty.
MMDSL/QC-0192	02/2024	01/2026	NS	50 Ampoules

RESULTS OF ANALYSIS

Reference to Protocol	IP-2022				
Description	Clear colourless liquid filled in amber coloured glass ampoules				
Test Parameters	Results				Limit
Identification :					
(A) by TLC	Complies				-
(B) by HPLC	Complies				-
Nominal Volume	2.0 ml				-
Extractable Volume	2.0 ml				-
pH	3.82				3.0 to 5.0
Composition of Gentamicin Sulphate (by HPLC)					
C1	27.1%				25.0 to 50.0%
C1a	27.4%				10.0 to 35.0%
C2+C2a	49.3%				25.0 to 55.0%
Bacterial endotoxins	Less than 1.67 EU/mg				NMT 1.67 EU/mg of gentamicin
Sterility	Complies				-
Assay (by MICRO)	Each ml contains:				
Particulars	Result	Claim	Lower	Upper	Method

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RESULTS OF ANALYSIS

		<u>Claim</u>	<u>Lower</u>	<u>Upper</u>	<u>Method</u>
Gentamicin Sulphate eq. to Gentamicin	9.87 mg	10.0 mg	9.5 mg	11.0 mg	IP-2022

End of Report

Remark: In the opinion of the undersigned the sample referred to above is of standard quality as defined in the Act
under for the reason given below ; Complies as per IP